

PETITION FOR EXTENSION OF TIME

Applicants hereby request a one-month extension of time extending the time for response from January 7, 1997 up to and including February 7, 1997. The Assistant Commissioner is hereby authorized to charge the required \$110.00 fee to Deposit Account No. 23-1703. Any additional fees due in connection with this Petition should likewise be charged.

Please amend the application as follows:

In the Claims:

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17. (twice amended) [A] The method [for the treatment of asthma and other inflammatory respiratory disorders, which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide] according to claim 17, wherein the effective amount of the physiologically acceptable salt of formoterol or solvate thereof is 6-100 µg per day, and the effective amount of budesonide is 50-4800 µg per day.

Please add the following new claims:

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29. The method according to any one of claims 17, 18 and 19, wherein the physiologically acceptable salt of

formoterol or the solvate thereof is administered in admixture with the budesonide.

⁹~~30~~. A medicament containing as active ingredients effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60.

¹²~~31~~. A pharmaceutical composition which comprises effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60, together with a pharmaceutically acceptable carrier.

²⁷~~32~~. A method for the treatment of asthma and other inflammatory respiratory disorders which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60.

¹⁰~~33~~. The medicament of claim ⁹~~30~~ wherein the active ingredients are in dry powder form.

¹¹~~34~~. The medicament of claim ⁹~~30~~ or ¹⁰~~33~~ wherein the formoterol is in the form of the fumarate dihydrate.

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~~35~~. The pharmaceutical composition of claim ¹²~~31~~ wherein the formoterol is in the form of the fumarate dihydrate.

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~~36~~. The method according to claim ²⁷~~32~~, wherein the effective amount of the physiologically acceptable salt of formoterol or solvate thereof is 6-100 μg per day, and the effective amount of budesonide is 50-4800 μg per day.

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~~37~~. The method according to claim ²⁸~~36~~ wherein the effective amount of the physiologically acceptable salt of formoterol or solvate thereof is 6-48 μg per day, and the effective amount of budesonide is 100-1600 μg per day.

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~~38~~. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~ and 37 wherein the administration is performed from a dry powder inhaler.

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~~39~~. The method according to claim ³⁰~~38~~ wherein the inhaler is a Turbuhaler™.

³²
~~40~~. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~ and ²⁹~~37~~ wherein the administration is performed from a metered dose inhaler.

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~~41~~. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~ and ²⁹~~37~~ wherein the formoterol is in the form of the fumarate dihydrate.

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¹²
~~42~~. A pharmaceutical composition according to claim ~~31~~ wherein the pharmaceutically acceptable carrier is lactose.